K-*ASSAY*®

Microalbumin Calibrator

Cat. No. KAI-020C

INTENDED USE

The **K-*ASSAY*®** Microalbumin Calibrator is for the calibration of the **K-*ASSAY*®** Microalbumin assay for quantifying albumin in urine specimens. FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

The calibrators in this kit are human albumin calibrators containing known quantities of human albumin. There is also a calibrator containing only diluent (150 mM sodium chloride). These calibrators are to be used with the **K-*ASSAY*®** Microalbumin assay.

KIT COMPOSITION

Calibrators (Liquid Stable)

Calibrator A:	150 mM Sodium Chloride	1 x 1 mL
Calibrator B-F:	Human Albumin 150 mM Sodium Chloride	5 x 1 mL

WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE. ℞ only.

Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed.

Albumin was isolated from pooled human serum that was tested and found negative for HBsAg, HCV, and HIV-1 antibodies by an FDA approved method. However, all products that contain human source material should be handled in accordance with good laboratory practices and appropriate control. See the National Institute of Health Manual, "Biosafety in Microbiology and Biomedical Laboratories," 2nd ed., 1988.

Do not mix or use calibrators from one test kit with those from a different lot number.

Do not use calibrators past their expiration date stated on each container label.

Do not pipette by mouth. Avoid ingestion and contact with skin.

Calibrators in this kit contain < 0.1% w/v sodium azide as a preservative. Sodium azide may form explosive compounds in lead drain lines. When disposing of calibrators through plumbing fixtures, flush with copious amounts of water. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts," in the Manual Guide-Safety Management No. CDC-22 issued by the Center for Disease Control, Atlanta, GA.

CALIBRATOR PREPARATION

The calibrators are ready to use and do not require reconstitution.

STORAGE AND HANDLING

All calibrators should be stored refrigerated (2-8°C). Return all calibrators to 2-8°C promptly after use. Unopened calibrators can be used for up to 18 months from the date of manufacture, as indicated by the expiration date on package and bottle labels.

CALIBRATOR STABILITY

Opened bottles of calibrators can be used for 1 month if stored at 2-8°C. Discard calibrators if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard.

Calibrator transferred to the instrument sample cup may concentrate over time. Therefore, calibrators should be capped and stored at 2-8°C when not in use. Otherwise, fresh calibrators should be used for each calibration.

INSTRUMENT

Measurements of absorbance are to be made with a clinical chemistry analyzer able to accurately read absorbance at 340 and 700 nm. Refer to the instrument manual from the manufacturer regarding the following:

a) Use or function
b) Installation procedures and requirements
c) Principles of operation
d) Performance characteristics, operating instructions
e) Calibration procedures including materials and / or equipment to be used
f) Operational precautions, limitations, and hazards
g) Service and maintenance information

PROCEDURE

Materials Supplied

Calibrators should be used as specified in the **K-*ASSAY*®** Microalbumin package insert.

Calibrator A	1 x 1 mL
Calibrator B	1 x 1 mL
Calibrator C	1 x 1 mL
Calibrator D	1 x 1 mL
Calibrator E	1 x 1 mL
Calibrator F	1 x 1 mL

Materials Required But Not Supplied

K-ASSAY® Microalbumin immunoturbidimetric assay

Two-Reagent Clinical Chemistry Analyzer:
Capable of accurate absorbance reading at 340/700 nm
Capable of accurately dispensing the required volumes
Capable of maintaining 37°C

Test Tubes: glass or plastic

Details of Procedure

NOTE: Allow reagents and specimens to come to room temperature. Mix all reagents gently before using.

K-ASSAY® Microalbumin Calibrators are assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the ***K-ASSAY®*** Microalbumin assay.

INTERFERENCE

Dust particles or other particulates in the reaction may result in extraneous light-scattering resulting in variable results.

CALIBRATOR VALUES

Albumin (mg/dL)

A	0.0
B	0.5
C	1.0
D	5.0
E	10.0
F	30.0

The values for ***K-ASSAY®*** Microalbumin Calibrator Set are continually being revised through ongoing quality assurance. As a result, the expected values may change from lot to lot. Please refer to the package insert for each lot for the exact calibrator values.

LABELING SYMBOLS

REF	Catalog Number
	Expiration or "Use By" Date
LOT	Lot Number
	Consult Package Insert for Instructions for Use
IVD	For *In Vitro* Diagnostic Use
CE	CE Mark Registered
℞	For Prescription Use Only
	Potential Human Biohazard
2°C 8°C	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
EC REP	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE

CE

EC REP

Advena Ltd.
Tower Business Centre, 2nd Flr.,
Tower Street, Swatar, BKR 4013 Malta

ORDERING / PRICING / TECHNICAL INFORMATION

KAMIYA BIOMEDICAL COMPANY
12779 Gateway Drive
Seattle, WA 98168 USA
TEL: (206) 575-8068 / (800) 526-4925
FAX: (206) 575-8094